FDA Risk Communication Advisory Committee Hilton Washington DC/Rockville, 1750 Rockville Pike Rockville, MD 20852

DISCUSSION TOPICS

May 16, 2008: Adverse Event Reporting Number Statement Study (Section 906)

- 1. Are you aware of research that is relevant to the task set before us by Congress in Section 906 of FDAAA? If so, please provide the research or alternatively, a bibliography.
- 2. Does the approach reflected in the materials provided seem like a reasonable approach to address the task set before FDA by Congress? In your answer, please address:
 - a. Sampling
 - b. Design
 - c. Proposed stimuli.